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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/705,195

11/10/2003

Volker Buttcher

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EXAMINER

PAGE, BRENT T

ART UNIT

PAPER NUMBER

1638

NOTIFICATION DATE

DELIVERY MODE

06/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/705,195	Applicant(s) BUTTCHEER ET AL.	
	Examiner BRENT PAGE	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 6-9, 15 and 16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52 and 54 is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-14, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Reply filed by Applicant on 04/28/2009 is hereby acknowledged. The Terminal Disclaimer has been approved. A conference for determining allowability was held and a closer inspection of the rules concerning written description and enablement has necessitated the following non-final action due to the breadth of the claims. Claims 1-55 are pending. Claims 6-9 and 15-16 remain withdrawn.

Claim Rejections - 35 USC § 112-enablement

Claims 1-5, 10-14, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53 and 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids and transforming plants comprising SEQ ID NO:1 or sequences encoding SEQ ID NO:2, does not reasonably provide enablement for all *Neisseria* branching enzymes that have as little as 95% identity to the first 100 amino acids depicted in SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a protein and a method for producing a branching enzyme, all of which comprise any nucleic acid molecule encoding any branching enzyme from a bacterium of the genus *Neisseria*, wherein the nucleic

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acid that encodes any protein that has a sequence wherein the first 100 amino acids have a homology of at least 95% to SEQ ID NO: 2.

In contrast, the specification only provides guidance for a full length branching enzyme from the *Neisseria denitrificans* species defined by SEQ ID NO 1. The specification does not provide guidance for any other nucleic acid sequences encoding a branching enzyme from a *Neisseria* species.

The branching enzyme polypeptide of the instant invention is 732 amino acids long. The claims as currently written only specify that within the first 100 amino acids that the polypeptide must be 95% identical to SEQ ID NO:2 and contain said motifs while the remaining 632 amino acids are unspecified.

Applicants have not given guidance on how to make and/or use polypeptides that only comprise a small portion of SEQ ID NO:2, and have the claimed activity without requiring one of skill in the art to practice undue trial and error experimentation, nor does the specification give guidance in the form of a single embodiment or detailed description of how such embodiments would be used to practice the invention. The specification only gives guidance for the isolation of the full length polypeptide and the characterization of its function as a branching enzyme and the prior art does not teach the conserved sequences of the branching enzymes from *Neisseria*. A list of peptide motifs without reference to their function or demonstrated required conservation among branching enzymes is not sufficient for guidance for the full scope of the claims, particularly wherein only the first 100 amino acids of the polypeptide are required to have any such motifs.

The unpredictability in the art recited in previous office actions is repeated here for clarity.

The function of starch branching enzymes is unpredictable. In a review of the regulation of starch metabolism in plants Tetlow et al (2004 Journal of Experimental Botany 55(406):2131-2145) disclose that only a few genetic variations that lead to known phenotypes are even known for starch branching enzymes as evidenced by the statement "To date, only mutations in SBEII isoforms give clear phenotypes, and in monocots this is confined to SBEIIb mutants" (see page 2134 second column, last paragraph). Tetlow et al disclose a mutant of SBEIIa that displayed a clear phenotype in leaf starch but showed no alterations in the storage starch of the endosperm (See page 2134 Column 2, last paragraph, for example). Tetlow et al further disclose that other genes are capable of affecting the expression of at least SBEIIb, but not all of these genes are known (see page 2135, 1st column, 3rd paragraph, for example). Without clear guidance as to a minimal sequence required for branching enzyme function, it would be undue experimentation for one of skill in the art to evaluate the claimed multitudes of sequences for their ability to encode branching enzymes as broadly claimed.

Given the state of the art, the disclosure by Tetlow et al and the unpredictability as disclosed above, and the breadth of the claims as discussed above, it would be undue experimentation for one of skill in the art to isolate and evaluate all Neisseria nucleic acids that encode branching enzymes as broadly claimed.

Claim Rejections - 35 USC § 112-written description

Claims 1-5, 10-14, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The only working example and described branching enzyme polypeptide of the instant invention is 732 amino acids long. The claims as currently written only specify that within the first 100 amino acids that the polypeptide must be 95% identical to SEQ ID NO:2 and contain said motifs while the remaining 632 amino acids are unspecified. The peptide motifs are not described in the specification in relation to the polypeptide function, and thus the requirement for an adequate written description of a genus branching enzymes from *Neisseria* that there be a correlation between structure and function, i.e conserved features and specific activity, has not been met. Moreover, Applicant has not described and the prior art does not support a description of a representative number of sequences that comprise the limitations of section (e) or (f) of claim 1 and that possess the activity of a glucan branching enzyme i.e. that produces α -1,6-branched α -1,4-glucans. The specification only describes the isolation of the full length polypeptide and the characterization of its function as a branching enzyme

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and the prior art does not teach the conserved sequences of the branching enzymes from *Neisseria*.

Double Patenting

The terminal disclaimer filed by Applicant on 04/28/2009 is hereby acknowledged and obviates the rejection of the claims under obviousness-type double patenting. The rejection of claims 1-5, 10-14, 17-22, 24-30, 37-44 and 51-55 is hereby withdrawn.

Claims 17-28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52 and 54 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/
Supervisory Patent Examiner, Art Unit 1638